UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF'NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER,

Plaintiffs and Relator,

-against-

No. 11 Civ. 8196 (CM)

NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION,

Defendants.

MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTIONS TO DISMISS

McMahon, J.:

In this *qui tam* action under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, the United States government ("the Government") intervened as a plaintiff against Novartis Pharmaceuticals Corporation ("Novartis"). The Government alleges that Novartis violated the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), in connection with a kickback scheme.

Pending before the Court are Defendant Novartis's motions to dismiss the Government's Amended Complaint-in-Intervention ("Complaint") for failure to state a claim pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure. For the reasons discussed below, these motions are granted in part and denied in part.[1]

BACKGROUND

The reader is presumed to be familiar with this Court's previous order denying Novartis's motion to dismiss the Complaint pursuant to Rule 9(b). *See U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.*, No. 11 Civ. 8196 (CM), 2014 WL 2324465 (S.D.N.Y. May 29, 2014) (hereafter "*Novartis I*").

The Government alleges that Novartis violated the FCA because it paid kickbacks to several pharmacies for promoting two drugs (Myfortic and Exjade) to physicians and patients in violation of the AKS. These pharmacies included Baylor Hospital, Bryant's Pharmacy, Kilgore's Medical Pharmacy, Transcript Pharmacy, Twenty-Ten Pharmacy, and BioScrip

[1] This opinion is to be referred to in all future correspondence and papers as "*Novartis IV*."

Corporation (collectively, "the pharmacies"). None of these pharmacies is a defendant in the Government's case.[2]

The AKS makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person" to "purchase or . . . recommend purchasing" a drug that is covered by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). Likewise, the AKS proscribes "knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate)" "in return for purchasing . . . or recommending purchasing" a drug covered by a federal health care program. *Id.* § 1320a-7b(b)(1). Thus, the AKS forbids offering, paying, soliciting, or receiving "remuneration" (*i.e.*, kickbacks) in exchange for recommending drugs covered by Medicare and Medicaid—which Myfortic and Exjade are (for patients eligible for those programs).

The Complaint alleges that Novartis paid kickbacks to the pharmacies to get them to recommend to physicians or patients that they prescribe/use Myfortic or Exjade. The Government alleges that Novartis paid the pharmacies two types of kickbacks during the course of the kickback schemes: (1) cash "rebates"[3] for each sale of Myfortic or Exjade, and (2) patient referrals (a form of "remuneration" under the AKS) in exchange for pharmacies' efforts to promote Exjade. Accordingly, the Government contends that both Novartis and the kickback-receiving pharmacies violated the AKS in connection with their dealings in Myfortic and Exjade; it argues that their noncompliance with the law rendered "false" all claims for those drugs that were submitted to Medicare and Medicaid programs.

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[2] BioScrip Corporation was originally named as a defendant in the Government's Complaint, but it settled out of the case in January 2014. *See* Docket No. 41.

[3] The cash rebates were sometimes labeled "discounts."

Based on these events, the Government asserts nine causes of action against Novartis. It asserts two counts under each of three different FCA subsections; one of the counts under each section is for the Myfortic scheme, and one count is for the Exjade scheme. Counts 1 and 5 assert causes of action under FCA subsection (a)(1)(A), Counts 2 and 6 assert causes of action under FCA subsection (a)(1)(B), and Counts 3 and 7 assert causes of action under FCA subsection (a)(1)(C).[4] *See* 31 U.S.C. §§ 3729(a)(1)(A)-(C). The Government also brings related state law claims: two counts of unjust enrichment (Counts 4 and 8)—one for each scheme—and one count of payment by mistake of fact (Count 9).

Novartis has moved twice to dismiss all claims; once under Rule 9(b) for failure to plead fraud with particularity, and once under Rule 12(b)(6) for failure to state a claim. In *Novartis I*, the Court effectively deferred decision on Novartis's Rule 9(b) motion until I could test the sufficiency of the Government's theory of "falsity" under the FCA. *See Novartis I*, 2014 WL 2324465, at *22.[5] This opinion addresses the sufficiency of the Government's theory.

DISCUSSION

I. Standard of Review

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable

[4] The Government also mentions the versions of these FCA subsections that were in effect prior to the enactment of the Fraud Enforcement and Recovery Act of 2009, which amended the FCA. That statutory amendment is explained in *Novartis I*. *See* 2014 WL 2324465, at *6-7. The statutory changes do not affect the outcome of this motion.

[5] To be precise, I denied the motion to dismiss pursuant to Rule 9(b) with leave to renew in light of this decision. As this decision effectively determines the sufficiency of the pleading under Rule 9(b)—it is sufficient—it will be futile to renew that motion.

inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

However, to survive a motion to dismiss, "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff's well-pleaded allegations have "nudged [its] claims across the line from conceivable to plausible, [the plaintiff's] complaint must be dismissed." *Id.* at 570; *see also Iqbal*, 556 U.S. at 680.

This liberal pleading standard is modified by Rule 9(b), which requires a plaintiff asserting fraud claims to meet a heightened pleading standard. While Rule 8(a) usually requires only a "short and plain statement of the claim showing that the pleader is entitled to relief," FED. R. CIV. P. 8(a), a plaintiff asserting fraud must "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Rule 9(b) applies to claims brought under the FCA. *See Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995).

II. The 2010 AKS Amendment Did Not Supersede the False Certification Theory of Claim "Falsity."

A. Legal "Falsity" Under *Mikes*

The Government's causes of action under the FCA require it to show that the Myfortic and Exjade claims the pharmacies submitted to government programs were "false or fraudulent."

As explained in *Novartis I*, subsection (a)(1)(A) of the FCA provides for liability where the defendant "knowingly presents, or causes to be presented, a *false or fraudulent claim* for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (emphasis added). To prove a claim under this subsection, a plaintiff must show that: (1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent, (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury. *See Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001); *U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010).

Subsection (a)(1)(B) provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a *false or fraudulent claim*." 31 U.S.C. § 3729(a)(1)(B) (emphasis added). To prove a claim under this subsection, a plaintiff must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false or fraudulent claim. *See Pervez*, 736 F. Supp. 2d at 811.

Subsection (a)(1)(C) provides for liability where the defendant "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)"—meaning conspires to commit a substantive FCA violation. 31 U.S.C. § 3729(a)(1)(C). In this case, the Government alleges that Novartis conspired with several pharmacies to violate subsections (a)(1)(A) and (a)(1)(B). To prove its subsection (a)(1)(C) claims, the Government must show: (1) an unlawful agreement by

the defendant to violate the FCA, and (2) at least one overt act performed in furtherance of that agreement. *See U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009); *U.S. ex rel. Sterling v. Health Ins. Plan of Greater New York, Inc.*, No. 06 Civ. 1141 (PAC), 2008 WL 4449448, at *4 (S.D.N.Y. Sept. 30, 2008).

Thus, all three subsections of the FCA at issue in this case require either the existence of "false or fraudulent" claims or a conspiracy involving "false or fraudulent" claims.

Defendant Novartis argues that the Government has not adequately pled that the claims at issue in this case were "false or fraudulent" within the meaning of the FCA. The question then becomes what makes a claim "false or fraudulent" for the purposes of the FCA; the statute itself provides no definition of those terms.

In *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), the Second Circuit established the definition of a "false or fraudulent" claim in this Circuit: it is any claim "aimed at extracting money the government otherwise would not have paid." *Id.* at 696. There are two types of "falsity"—*i.e.*, two reasons that the government would not pay the claim if it knew the true facts. One is factual falsity; the other is legal falsity. *See id.* at 697.

A claim is "factually false" where the party submitting the claim supplies "an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*; *see also Pervez*, 736 F. Supp. 2d at 812. In other words, the party "bills for something it did not provide." *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011). No such claim is alleged here.

In contrast, a "legally false" claim is "false" because it has been tainted by some underlying statutory, regulatory, or contractual violation made in connection with that claim,

which renders the claim ineligible for reimbursement. Under *Mikes*, a violation does not render a claim "false" unless (1) compliance with the underlying statute, regulation, or contract is a "precondition" to payment of the claim, and (2) a party falsely represents (or "certifies") compliance with the provision in connection with the claim. 274 F.3d at 697-98. The *Mikes* court distinguished between preconditions to *payment* of claims and mere conditions of *participation* in a government program; in order for a statutory violation to provide a basis for legal "falsity," the government's decision to reimburse the claim must be conditioned upon compliance with the underlying statute. *See id.* at 701-02. The preconditions to payment vary by government program.

Mikes set forth the analytical framework for the "false certification" theory of legal "falsity." *See id.* at 697-99. Under this theory, a claim is rendered "false" (and thus, ineligible for reimbursement) where the party submitting the claim falsely "certifies" compliance with a statutory, regulatory, or contractual provision, and that compliance is a precondition to payment of the claim. *See id.* at 697. There are two types of false certifications: express and implied.

As the name suggests, an "express false certification" occurs when the party submitting the claim expressly and "falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* at 698. Generally, express certifications arise when a government program requires participants to submit forms explicitly stating that they have complied with certain statutes. *See id.* Where the party certifying compliance is, in fact, violating the statute in question, that certification is "false." The claims rendered legally "false" by such false certifications include all the claims connected to the underlying statutory violation.

Legal "falsity" can also arise on a theory of "implied false certification." The implied false certification theory is "based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* at 699. In *Mikes*, the Second Circuit stated that this theory "is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant." *Id.*

The "false certification" theory of legal "falsity" articulated in *Mikes* has been widely adopted among the Circuits. *See U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 306 (3d Cir. 2011); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467 (6th Cir. 2011); *U.S. ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1167-71 (10th Cir. 2010); *Ebeid ex rel. U.S. v. Lungwitz*, 616 F.3d 993, 996-98 (9th Cir. 2010); *U.S. v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010); *U.S. ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604 (7th Cir. 2005); *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005); *U.S. ex rel. Siewick v. Jamieson Sci. & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786-87 (4th Cir. 1999); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996).

As discussed in *Novartis I*, Congress amended the FCA in 2009. *See* 2014 WL 2324465, at *6-7. However, it did not alter the "false or fraudulent" language in the FCA or define those terms in some way inconsistent with *Mikes* and its progeny. *Mikes* has been neither abrogated

nor overturned by the Supreme Court, and the Second Circuit reaffirmed its "false certification" theory of claim falsity in April 2010 in *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94 (2d Cir. 2010), *rev'd on other grounds*, 131 S. Ct. 1885 (2011). Thus, *Mikes*'s holding that a claim is "false or fraudulent" if the party submitting the claim falsely certifies that it is in compliance with a law that is a precondition to payment is still controlling law in this Circuit; it binds this Court. As long as the Government's allegations meet the *Mikes* standard, I cannot dismiss the Government's Complaint.

Here, the Government invokes *Mikes*. It asserts that the claims for Myfortic and Exjade that were submitted by pharmacies involved in the kickback schemes were legally "false," because they were tainted by the AKS violations committed by those pharmacies and Novartis.

First, the Government contends that compliance with the AKS is a precondition to the payment of Medicare and Medicaid claims. *See* Pl. Opp. at 17. Courts have long held that this is the case. *See U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 394 (1st Cir. 2011) ("If kickbacks affected the transaction underlying a claim . . . the claim failed to meet a condition of payment"); *see also U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 313 (3d Cir. 2011); *New York v. Amgen Inc.*, 652 F.3d 103, 111-13 (1st Cir. 2011); *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005); *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d Cir. 2004); *Hericks v. Lincare Inc.*, No. 07 Civ. 387, 2014 WL 1225660, at *4 (E.D. Pa. Mar. 25, 2014); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 662-63 (S.D. Tex. 2013); *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09 Civ. 22253, 2013 WL 1289260, at *4 (S.D. Fla. Mar. 27, 2013); *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008); *U.S. ex rel. Fry v. The Health Alliance of Greater Cincinnati*, No. 03 Civ. 167, 2008 WL 5282139, *12 (S.D. Ohio, Dec. 18,

2008); *U.S. v. Rogan*, 459 F. Supp. 2d 692, 717 (N.D. Ill. 2006); *U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 32 (D.D.C. 2003); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998).

As discussed in *Novartis I*, in 2010 Congress eliminated any doubt that compliance with the AKS is a precondition to the payment of Medicare and Medicaid claims. *See* 2014 WL 2324465, at *24. As part of the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), Congress amended the AKS to state: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). The AKS applies to all "Federal health care program[s]," including Medicare and Medicaid. *Id.* § 1320a-7b(f). Thus, the 2010 amendment made clear that compliance with the AKS is a precondition to the payment of claims submitted to these programs, and not merely a condition of participation in the programs.

Novartis does not dispute that compliance with the AKS is a precondition to the reimbursement of claims submitted to Medicare and Medicaid.

Second, the Government asserts that, in connection with claims submitted to Medicare and Medicaid, the pharmacies were required to certify (either expressly or impliedly) that they were in compliance with applicable federal statutes as a precondition to reimbursement of the claims. Some of the forms on which pharmacies "expressly" certified compliance specifically mentioned the AKS; others certified that the pharmacies were in compliance with "all applicable" federal laws, which would necessarily include the AKS. And the pharmacies also "impliedly" certified compliance with the AKS through the act of submitting the claims for reimbursement.

Third, the Government alleges that Novartis and the pharmacies were violating the AKS in connection with all the claims for Myfortic and Exjade that the pharmacies submitted during the course of the kickback schemes because (1) Novartis entered into kickback arrangements with the pharmacies to promote Myfortic and Exjade, (2) Novartis paid the pharmacies rebates (*i.e.*, kickbacks) on every single sale of Myfortic or Exjade, and (3) Novartis referred Exjade patients to the pharmacies in exchange for promotional services. According to the Government, this rendered the pharmacies' certifications of compliance with the AKS "false" as to their sales of Myfortic and Exjade, and these false certifications in turn rendered all the corresponding claims "false." Pl. Opp. at 3.

B. 2010 AKS Amendment

Novartis challenges the Government's "sweeping theory" of falsity. Def. Br. at 20. Novartis argues that the AKS (not the FCA) was amended by the PPACA in 2010, and that this amendment narrowed the category of claims that could be rendered "false" by underlying AKS violations by adding Section 1320a-7b(g), which provides: "In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services *resulting from* a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g) (emphasis added).

Novartis argues that this new language clarified the reach of the FCA in the AKS context and so rendered *Mikes* inapplicable when the underlying statute that was allegedly violated is the AKS. It seizes on the phrase "resulting from" in Section 1320a-7b(g), and argues that the only claims that can be rendered "false" by underlying AKS violations are those claims for medical goods or services that "result[] from" such violations. In Novartis's view, a claim for Myfortic or Exjade is not "false" unless the Government can show that a kickback-receiving pharmacy's

sale of that drug to a particular patient was actually *caused* by the kickback scheme. Novartis further argues that a drug sale was only caused by the kickback scheme where the scheme succeeded in achieving its goal—*i.e.*, where a pharmacy convinced a physician (in the case of Myfortic) to prescribe a drug that he would not have otherwise prescribed, or convinced a patient (in the case of Exjade) to order a refill that he would not have otherwise ordered.

In short, Novartis contends that it is not enough that a pharmacy received kickbacks for promoting a particular drug (Myfortic or Exjade) and then submitted claims for reimbursement for that drug after falsely certifying that it was in compliance with the AKS—even though this is sufficient to render a claim "false" under *Mikes*.

In effect, Novartis argues that the 2010 AKS amendment that was included in the PPACA did away with *Mikes*'s definition of "falsity" under the FCA and substituted a strict "but for" causation requirement on a transaction-by-transaction, claim-by-claim basis. Of course, the amendment did not go into effect until 2010, and it is not retroactive. *See U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 n.4 (D. Mass. 2011). But Novartis argues that the amendment was intended only to clarify what the law had *always* been: that AKS violations can only give rise to legally "false" claims where the decision to provide medical treatment is caused by a kickback scheme. *See* Def. Br. at 9.

Novartis is essentially arguing that *Mikes* was wrongly decided. I cannot very well reach that conclusion, given that *Mikes* is binding Second Circuit case law.

But I reject the notion that the 2010 AKS amendment was intended to narrow the scope of "false" claims predicated on underlying AKS violations. I also reject any suggestion that it was intended to do away with *Mikes* and its progeny.

There is no indication in either the law itself or the legislative history that Congress intended to narrow the scope of "falsity" under the FCA when it amended the AKS to add Section 1320a-7b(g). As a canon of statutory interpretation, courts "assume that, when Congress enacts statutes, it is aware of relevant judicial precedent." *Merck & Co., Inc. v. Reynolds*, 559 U.S. 633, 648 (2010). In enacting the PPACA, Congress legislated against the backdrop of *Mikes* and its progeny—literally hundreds of cases around the country that interpreted the word "false" in the FCA to include claims submitted under false pretenses of any kind—including "false certifications" of compliance with statutes that are preconditions to payment. Congress gave absolutely no indication that it intended to amend the definition of the word "false" in the FCA, or to limit the FCA's reach where kickbacks were concerned.

The legislative history of the 2010 AKS amendment (Section 1320a-7b(g)) demonstrates that the new provision was intended to do anything but narrow existing law. Rather, Congress corrected a single district court decision that the sponsors of the predecessor bill feared construed the *Mikes* "false certification" theory of FCA liability too narrowly in the AKS context.

The predecessor bill containing Section 1320a-7b(g) (which was eventually incorporated into the PPACA) was called the "Health Care Fraud Enforcement Act of 2009." S. 1949 (111th Cong., 1st Sess., 2009), http://www.gpo.gov/fdsys/pkg/BILLS-111s1959is/pdf/BILLS-111s1959is.pdf. Its stated purpose was "To improve health care fraud enforcement." *Id.* Besides adding Section 1320a-7b(g) to the AKS, the bill updated the definition of "health care fraud offense" in the federal criminal code to include violations of the AKS and other statutes. The bill also contained provisions providing harsher sentences for health care fraud offenses, more relaxed scienter requirements for such offenses, and additional enforcement funding for the Department of Justice ("DOJ"). *See id.*

A sponsor of the Health Care Fraud Enforcement Act, Senator Ted Kaufman, stated that the bill would "strengthen[] whistleblower actions based on medical care kickbacks." 155 Cong. Rec. S10852-01, 2009 WL 3460582 (daily ed. Oct. 28, 2009) (Sen. Kaufman). In a floor speech, Senator Kaufman stated: "The Department of Justice has had success both prosecuting illegal kickbacks and pursuing False Claims Act matters based on underlying violations of the Anti-Kickback Statute. Nevertheless, defendants in such FCA cases continue to mount legal challenges that sometimes defeat legitimate enforcement efforts." *Id.* Thus, Senator Kaufman explicitly acknowledged (and championed) the "success" that the DOJ had had in utilizing the false certification theory of claim "falsity" in the AKS context. *Id.*

Senator Kaufman then discussed the district court's holding in *United States ex rel. Thomas v. Bailey*, No. 06 Civ. 465, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008), a case in which the FCA was interpreted in the AKS context. In *Thomas*, a surgeon allegedly entered into a "consulting agreement" with a medical device company and its sales representative, wherein the surgeon received kickbacks in exchange for using the company's devices in his surgeries. The surgeon would instruct the hospital at which he performed surgeries (but was not employed) to order the device company's products. The surgeon then submitted claims to federal programs for his surgical services, while the hospital submitted separate claims for the medical devices he used in the surgeries.

A relator brought FCA claims against, *inter alia*, the surgeon, the sales representative, and the device company; the hospital had no knowledge of the kickback scheme, so it was not a named defendant. The surgeon settled out of the case, but the relator proceeded against the sales representative and the device company on the theory that they had "caused" the hospital to

submit false claims—much as Novartis is here accused of "causing" the pharmacies to submit false claims.

Citing *Mikes* and other cases, the *Thomas* court applied the false certification theory of claim "falsity." It concluded that the surgeon's claims for his services (which he submitted) were "false" claims, because compliance with the AKS was a precondition to the reimbursement of claims, and the surgeon "impliedly" certified to his own compliance with the AKS through the act of submitting the claims. So even though the surgeon performed the surgeries for which he submitted claims—that is, even though his claim was not "factually" false—he impliedly certified that he had complied with the AKS by submitting the claims. As he was allegedly not in compliance with the AKS, his implied certification to the contrary rendered the claim legally "false" within the meaning of *Mikes*.

However, the *Thomas* court held that the remaining defendants could not be held liable on the theory that they "caused" the innocent hospital to submit false claims for reimbursement for the medical devices, because the claims submitted by the hospital were neither factually false nor legally false under *Mikes* (whose theory of express and implied false certification the court applied).

The medical device was actually implanted into the patient, so the claim was factually true—the service was in fact provided.

The *Thomas* court reasoned that the claims were not rendered false by an "implied" false certification because, when the hospital submitted its claims, it was only impliedly certifying its *own* compliance with underlying law (including the AKS)—not the compliance of the surgeon who performed the procedure. *See id.* at *9.

Finally, the *Thomas* court concluded that the claims submitted by the hospital were not rendered false by any "express" false certification, because of the precise language used on the certification forms signed by the hospital. Those forms said, "[T]o the best of [the hospital administrator's] knowledge and belief . . . the services identified in this cost report were provided in compliance with" applicable laws, including the AKS. *Id.* at *10. That was literally true—the hospital administrator did not know about the kickback scheme involving the surgeon and the device maker, so to the best of his knowledge and belief, there was no lack of compliance with relevant laws. The *Thomas* court recognized that an innocent party like the hospital could unknowingly submit "false" claims, *see id.* at *11 (citing *U.S. v. Bornstein*, 423 U.S. 303 (1976)), but reasoned that the wording of the certification form, which focused on the hospital administrator's knowledge and belief, precluded such a finding in the particular case before him.

Senator Kaufman disapproved of the *Thomas* court's holding that the claims submitted by the hospital were not "false." He stated:

> [A] court recently held that, even though a device company may have paid a kickback to a doctor to use a particular medical device, the bill to the government for the procedure to implant the device was not false or fraudulent because the claim was submitted by the innocent hospital, and not by the guilty doctor. In other words, a claim that results from a kickback and that is fraudulent when submitted by a wrongdoer is laundered into a "clean" claim when an innocent third party finally submits the claim to the government for payment. This has the effect of insulating both the payor and the recipient of the kickback from False Claims Act liability. This obstacle to a successful action particularly limits the ability of the Department of Justice to recover from pharmaceutical and device manufacturers, because in such instances the claims arising from the illegal kickbacks typically are not submitted by the doctors who received the kickbacks, but by pharmacies and hospitals that had no knowledge of the underlying unlawful conduct.

155 Cong. Rec. S10852-01, 2009 WL 3460582. Senator Kaufman went on to explain that the Health Care Fraud Enforcement Act "remedies the problem by amending the anti-kickback

statute to ensure that all claims resulting from illegal kickbacks are 'false or fraudulent,' even when the claims are not submitted directly by the wrongdoers themselves." *Id.* Another sponsor of the bill, Senator Patrick Leahy, echoed this statement regarding the purpose of the provision that later became Section 1320a-7b(g). *See id.*

The legislative history of Section 1320a-7b(g) makes it completely clear that Congress only intended that provision to correct *Thomas*'s strict interpretation of the false certification theory. The *Thomas* court had, in effect, allowed the submission of a kickback-tainted claim by an innocent party to "launder[] [it] into a 'clean' claim." *Id.* By enacting Section 1320a-7b(g), Congress made clear that the fact that the certifications were made by an innocent party submitting a claim without knowledge of an AKS violation did not remove the taint of falsity from the certifications; any claim connected in any way to an AKS violation was ineligible for reimbursement, even if the party that submitted the claim had no knowledge of the AKS violation.

The new provision did nothing to alter the false certification theory of claim "falsity" articulated in *Mikes* and its progeny. Since the enactment of the PPACA, courts have continued to employ this framework in FCA cases predicated on AKS violations. *See U.S. ex rel. Williams v. Health Management Assocs., Inc.*, No. 09 Civ. 130, 2014 WL 2866250, at *16-18 (M.D. Ga. June 24, 2014); *U.S. ex rel. Ruscher v. Omnicare, Inc.*, No. 08 Civ. 3396, 2014 WL 2618158, at *7 (S.D. Tex. June 12, 2014); *Parikh*, 977 F. Supp. 2d at 663-64; *Osheroff*, 2013 WL 1289260, at *3-7; *U.S. ex rel. Yarberry v. Sears Holdings Corp.*, No. 09 Civ. 588, 2013 WL 1287058, at *3 (S.D. Ill. Mar. 28, 2013). And here, the Government accuses the pharmacies that submitted the claims of violating the AKS, so the 2010 AKS amendment is utterly irrelevant. No claims in this case are alleged to have been submitted by "innocent" parties.

Until the Second Circuit decides otherwise, *Mikes*'s interpretation of the words "false or fraudulent" in the FCA remains intact where a plaintiff asserts the submission of "false" claims based on underlying AKS violations. Where a party falsely certifies compliance with the AKS (either expressly or impliedly) in connection with a claim, the claim is "false" as a matter of law, and so is not eligible for reimbursement.

As discussed below, the Government has sufficiently pleaded that many of the Myfortic and Exjade claims submitted by the pharmacies were rendered legally "false" by the pharmacies' false certifications of compliance with the AKS. *See infra* at § III. Because the Government's theory of claim "falsity" is legally sufficient for those claims, Novartis's arguments regarding the Government's failure to plead fraud with particularity fail; the Complaint adequately identifies the claims at issue. *See Novartis I*, 2014 WL 2324465, at *23-25. Therefore, on both Rule 12(b)(6) and Rule 9(b) grounds, the motions to dismiss are granted in part and denied in part.

III. The Government Has Adequately Pled That Many of the Claims Submitted to Medicare and Medicaid Programs Were "False."

Novartis makes little effort to challenge the particular false certifications identified by the Government. In a footnote, Novartis merely incorporates by reference the arguments made by Accredo and Curascript—two pharmacies that are named as defendants in the Relator's complaint, but not the Government's complaint—in their brief in support of their motion to dismiss the Relator's complaint; these defendants argue that the Relator fails to identify express or implied false certifications that rendered the claims they submitted "false" prior to the enactment of the PPACA in March 2010. *See* Docket No. 178 at 10-17. Novartis contends that these arguments "apply with equal force" to the Government's Complaint. Def. Br. at 15 n.3.

A. Express False Certifications

In the Complaint, the Government identifies several express certifications of AKS compliance that the pharmacies made in connection with claims submitted during the course of the kickback schemes. It contends that these certifications were false, given the pharmacies' involvement in the schemes, and that these false certifications rendered the claims for Myfortic and Exjade "false."

1. Medicare Part B Claims

As discussed in *Novartis I*, the Government alleges that Medicare Part B, which reimbursed claims for Myfortic (not Exjade), required participating pharmacies (the "providers" or "suppliers") to enter into provider agreements on the Centers for Medicare and Medicaid Services ("CMS") Form 855S. These agreements contained the following certifications:

> I agree to abide by the Social Security Act and *all applicable Medicare laws, regulations and program instructions* that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that *payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with* such laws, regulations, and program instructions (including, but not limited to, the *Federal anti-kickback statute* and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Compl.[6] ¶ 23 (emphasis added).

The language in CMS Form 855S is clearly sufficient to constitute an express certification of compliance with the AKS. The certification not only states that the provider must comply with "all applicable Medicare laws, regulations and program instructions," but also explicitly mentions that the "Federal anti-kickback statute" is one of these laws. *Id.* The form

[6] "Compl." refers to the Government's Amended Complaint-in-Intervention.

also reminds providers that compliance with the AKS is "condition" of claim reimbursement under Medicare. *Id.*

The Government here asserts that the pharmacies that participated in the Myfortic kickback scheme certified compliance with the AKS via CMS Form 855S, and that these certifications were "false" because the pharmacies did not, in fact, comply with the AKS in connection with the "underlying transactions" (*i.e.* drug sales to particular patients). Rather, Novartis was paying the pharmacies a kickback for every Myfortic sale they made—meaning all claims for Myfortic were "false," because the kickback-receiving pharmacies submitted these claims under false pretenses.

Novartis argues that the certifications in CMS Form 855S "imply a causal nexus by referring to payments 'conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions'." Def. Br. at 15 n.3. Essentially, Novartis argues that the pharmacy receiving the kickback must have caused a particular doctor to prescribe Myfortic to a particular patient in order for the claim to be rendered "false" by virtue of this express certification.

Novartis is wrong. The form does not use any language suggesting a causation requirement; it focuses only on the behavior of the provider. It requires the provider to certify that it complied with the AKS in connection with both the "claim" and the "underlying transaction." Compl. ¶ 23. The pharmacies' alleged failure to comply with the AKS in completing the "underlying transaction" (*i.e.*, the drug sale) is exactly what the Government alleges in this case.

Other courts have held that a party's submission of a CMS form with language that is virtually identical to the certification contained in CMS Form 855S renders a claim "false,"

where the party was allegedly violating the AKS in connection with the underlying transaction that is the subject of that claim. *See Hutcheson*, 647 F.3d at 392-94; *Ruscher*, 2014 WL 2618158, at *18-20; *Osheroff*, 2013 WL 1289260, at *3-4; *Pogue*, 565 F. Supp. 2d at 159.

Thus, the Government has adequately alleged that all the Myfortic claims the pharmacies submitted to Medicare Part B during the course of the kickback scheme were rendered "false" by their express certifications in CMS Form 855S.

2. Medicare Part D Claims

The Government also alleges that Medicare Part D, which reimbursed claims for Exjade (not Myfortic), required participating pharmacies to make express certifications of compliance with the AKS as a precondition to reimbursement.

Specifically, the Department of Health and Human Services ("HHS"), through its component agency CMS, contracts with private companies ("Part D plan sponsors") to administer prescription drug plans. Pursuant to CMS regulations, Part D plan sponsors must agree to comply with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. 3729 et seq.), and the *anti-kickback statute* (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1) (emphasis added).

Part D plan sponsors, in turn, enter into subcontracts with pharmacies (including those involved in the kickback scheme) to provide drugs to Medicare Part D beneficiaries. The Complaint alleges that, per CMS regulations, the pharmacies' subcontracts with Part D plan sponsors contained language "obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions." Compl. ¶¶ 28-29. As the source of this requirement, the Complaint specifically cites 42 C.F.R. § 423.505(i)(4)(iv), which states: "Each and every

contract must specify that the related entity, contractor, or subcontractor must comply with all applicable Federal laws, regulations, and CMS instructions." The pharmacies' certifications in these subcontracts are the express certifications at issue.

The AKS is unquestionably one of the "applicable Federal laws" governing Medicare Part D that is cited in the subcontract certification. CMS regulations specifically identify the AKS as one of the "Federal laws and regulations designed to prevent fraud, waste, and abuse" that apply to Medicare Part D. 42 C.F.R. § 423.505(h)(1). Moreover, the AKS itself states that it applies to any "Federal health care program," which includes Medicare Part D. 42 U.S.C. § 1320a-7b(f).

Accordingly, subcontracting pharmacies who certify compliance "with all applicable Federal laws, regulations, and CMS instructions" certify compliance with the AKS. 42 C.F.R. § 423.505(i)(4)(iv). The Government alleges that the pharmacies participating in the Exjade scheme made such express certifications, and that these certifications were "false," given that the pharmacies were actually violating the AKS by receiving kickbacks in the form of both patient referrals and rebates on Exjade sales in exchange for recommending refills to patients. Thus, the false certifications rendered all the claims for Exjade "false."

Novartis does not challenge the substance of the pharmacies' subcontracts with Part D plan sponsors as express certifications of AKS compliance. Rather, Novartis argues that these contracts cannot constitute a basis for *implied* certifications under *Mikes*, since the CMS regulations cited by the Government do not expressly state that compliance with the AKS is a

precondition to the payment of claims submitted to Medicare Part D, as opposed to a mere condition of participation in the program.[7]

Novartis is correct that *Mikes* held that the implied certification theory "is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." 274 F.3d at 700 (emphasis in original). But the Government is invoking an *express* certification argument here, not an implied certification argument. *Mikes* only imposed the strict rule requiring an underlying statute to "expressly" state that it is a precondition to payment where the plaintiff asserts that a party *impliedly* (not expressly) certified compliance with that statute. *Id.* As long as compliance with the AKS is a precondition to the payment of claims under Medicare Part D—which Novartis does not dispute—a pharmacy's express false certification of compliance with the AKS renders claims "false," regardless of whether the AKS or any regulation explicitly states that such compliance is a precondition to payment.

The Government has adequately alleged that all the Exjade claims the pharmacies submitted to Medicare Part D during the course of the kickback scheme were rendered "false" by the express certifications of AKS compliance that they made in their subcontracts with Part D plan sponsors.

3. State Medicaid Claims

The Government alleges that state Medicaid programs, which paid for both Myfortic and Exjade claims, required participating pharmacies to make express certifications of compliance with the AKS in their Medicaid enrollment agreements. *See* Compl. ¶ 36. The Government

[7] As explained above, Novartis does not make these arguments directly; it incorporates the arguments made by Accredo and Curascript in support of their motion to dismiss the Relator's complaint. *See* Def. Br. at 15 n.3.

acknowledges that there are "variations among the states" in the content of these agreements, but asserts that "many states" require such express certifications as a condition of payment. *Id.* at ¶¶ 36-37.

However, the only such certification that the Government actually references in the Complaint is the "Certification Statement for Provider Billing Medicaid" that is required by New York Medicaid. The Government alleges that providers (like pharmacies) must "periodically" certify compliance in connection with the claims they submit to that program, stating: "I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations." *Id.* at ¶ 38. The AKS is an "applicable" federal law since Medicaid is one of the "Federal health care program[s]," to which the AKS applies. 42 U.S.C. § 1320a-7b(f).

The Government alleges that the pharmacies that participated in the Myfortic and Exjade schemes made such certifications to the New York Medicaid program, and that these certifications were false, since they did not "furnish[] the . . . supplies itemized . . . in accordance with" the AKS. Compl. ¶ 38. Rather, they received kickbacks on all sales of Myfortic and Exjade.

Novartis does not challenge the sufficiency of the express certifications that the pharmacies made in their New York Medicaid enrollment agreements.[8] Thus, the Government adequately alleges that the claims the pharmacies submitted to this program were rendered "false" by the false AKS compliance certifications contained in the pharmacies' New York Medicaid enrollment agreements.

[8] Again, I am referring to the arguments made by Accredo and Curascript that were incorporated by Novartis. *See* Def. Br. at 15 n.3.

However, as to the rest of the state Medicaid programs, the Government offers only conclusory allegations that "many states" require express AKS compliance certifications. *Id.* at ¶ 36. The Government pleads no facts supporting this general assertion. Without more, these allegations are insufficient to plead an express false certification. Under *Mikes*, the Government's FCA claims relating to the claims submitted to state Medicaid programs (other than New York's) may only go forward if they were rendered false by "implied" false certifications.

B. Implied False Certifications

The Government also alleges that the pharmacies made implied certifications of AKS compliance when they submitted claims to Medicare Part B, Medicare Part D, and state Medicaid programs.

As discussed above, *see supra* at § III.A.2, the Second Circuit has limited use of the implied false certification theory to instances "when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in original). As Novartis points out, the AKS did not explicitly state that it was a precondition to the payment of Medicare and Medicaid claims (as opposed to a mere condition of program participation) until the enactment of the PPACA on March 23, 2010. After that point, Section 1320a-7b(g) expressly stated that violating the AKS rendered claims "false" under the FCA—in other words, that AKS compliance is a precondition to the payment of any claims. *See* 42 U.S.C. § 1320a-7b(g).

Accordingly, from and after March 2010 "the act of submitting a claim for reimbursement itself implie[d] compliance with" the AKS, *Mikes*, 274 F.3d at 699, even in absence of any express certification of compliance. Thus, pharmacies that submitted claims to

any federal health care program—including Medicare Part B, Medicare Part D, and all state Medicaid programs—impliedly certified that they complied with the AKS in connection with those drug sales.

The Government alleges that, for pharmacies participating in the kickback schemes, each of these implied compliance certifications was "false" for their Myfortic and Exjade claims, given that the pharmacies were actually accepting kickbacks on each of the underlying sales of those drugs.

Novartis does not challenge the sufficiency of the Government's implied certification theory for claims submitted after the enactment of the PPACA.[9] Thus, the Government sufficiently alleges that, beginning on March 23, 2010, the pharmacies that participated in the kickback schemes made implied false certifications of AKS compliance that rendered the claims for Myfortic and Exjade that they submitted to all Medicare and Medicaid programs "false."

However, the Government does not contend that the AKS expressly stated that compliance with that statute was a precondition to the payment of Medicare and Medicaid claims (as opposed to a condition of program participation) prior to March 23, 2010. Accordingly, the Government has failed to allege that the pharmacies made implied false certifications with the AKS that rendered the claims they submitted prior to that date "false." *See Mikes*, 274 F.3d at 700; *U.S. ex rel. Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, No. 00 Civ. 4863, 2003 U.S. Dist. LEXIS 27469 at *23 (E.D. Pa. Aug. 14, 2003) (E.D. Pa. Nov. 21, 2003).[10]

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[9] Accredo and Curascript essentially admit that these implied certifications were sufficient to render the claims they submitted to federal programs after the enactment of the PPACA on March 23, 2010 "false" under *Mikes*. Those parties only challenge the Relator's implied certification theory as to claims submitted before that date. Novartis incorporates these arguments by reference. *See* Def. Br. at 15 n.3.

[10] The Government references a New York regulation that could be deemed a basis for implied false certifications of AKS compliance prior to March 2010. *See* Compl. ¶ 35 (citing N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c)). However, this Court need not decide whether this regulation qualifies as an

This fact is immaterial for the claims submitted to Medicare Part B, Medicare Part D, and New York Medicaid prior to March 2010, since the Government adequately alleges that the pharmacies made express false certifications that encompassed those claims, rendering them "false." *See supra* at §§ III.A.

Because the Government has failed to allege any express or implied false certifications made in connection with the claims submitted to state Medicaid programs (other than New York's) prior to the enactment of the PPACA on March 23, 2010, the Government's FCA claims (Counts 1, 2, 3, 5, 6, and 7) must be dismissed insofar as they relate to those claims for repayment. This dismissal is without prejudice. The Government has 21 days to replead its claims, invoking the specific certification forms, statutes, or regulations that provide a basis upon which this Court can find that false certifications (either express or implied) rendered those claims "false."

IV. The Government Has Adequately Pled Its State Law Claims.

Though Novartis moves to dismiss all claims, it makes no arguments in support of its motion to dismiss the three state law claims—Counts 4, 8, and 9. Presumably, Novartis assumes that, if this Court dismisses the federal claims, it will decline to exercise supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(c).

Because federal claims remain, the Court will not dismiss the state law claims.

"underlying statute or regulation . . . [that] *expressly* states the provider must comply in order to be paid." *Mikes*, 274 F.3d at 700 (emphasis in original); the Government has adequately alleged that the pharmacies made express false certifications of AKS compliance that rendered the claims they submitted to New York Medicaid prior to March 2010 "false." The Government does not reference any similar statutes or regulations for any other states that could make a difference in this case.

CONCLUSION

For the foregoing reasons, Novartis's motions to dismiss the Government's Complaint pursuant to Rules 12(b)(6) and 9(b) are granted in part and denied in part. The Government may proceed on its FCA claims (Counts 1, 2, 3, 5, 6, and 7) insofar as they relate to claims for Myfortic and Exjade submitted to Medicare Part B, Medicare Part D, and New York Medicaid for the entire period in question. It may also proceed on its FCA claims insofar as they relate to claims for Myfortic and Exjade submitted to other state Medicaid programs from and after March 23, 2010. The FCA claims are otherwise dismissed without prejudice. The motions to dismiss are denied as to the state law claims (Counts 4, 8, and 9).

The Clerk of the Court is directed to close out the motions at Docket Nos. 137 and 202 and to remove same from the Court's list of pending motions.

Dated: August 7, 2014

U.S.D.J.

BY ECF TO ALL COUNSEL